

**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Applicant:** Joan Fallon

**Serial No.:** unassigned

**Filed:** Concurrently herewith

**Docket:** 8016-1DIV

**For: METHODS FOR TREATING PERVASIVE DEVELOPMENT DISORDERS**

Assistant Commissioner for Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Prior to examination on the merits of the above Divisional Application, please amend the above-identified application as follows:

**IN THE SPECIFICATION:**

On page 1, on a new line after the title, please insert the following paragraph:

**-- Cross-Reference To Related Application**

This application is a Divisional of U.S. Application Serial No. 09/466,559, filed on December 17, 1999. --

A marked-up version illustrating the above specification amendment is annexed hereto.

**IN THE CLAIMS:**

Please cancel claims 6-24 without prejudice.

**Please add the following New claims:**

25. (New) A method for determining if a patient has, or can develop, a PDD, comprising the steps of:

obtaining a stool sample from the patient;

analyzing a compound in the stool sample of the patient; and

correlating the analysis of the compound with a PDD condition or lack thereof.

26. (New) The method of claim 25, wherein the compound comprises an indicator of protein digestion.

27. (New) The method of claim 25, wherein the compound comprises an indicator of pancreatic function.

28. (New) The method of claim 25, wherein the compound comprises chymotrypsin.

29. (New) The method of claim 25, wherein the PDD comprises autism.

30. (New) The method of claim 25, wherein the step of analyzing comprises the step of determining a quantity of the compound in the stool sample.

31. (New) The method of claim 30, wherein the step of correlating comprises the step of comparing the quantity of the compound in the stool sample of the patient with a normal quantity of the compound found in a non-PDD individual.

32. (New) A biological marker for determining if an individual has, or can develop, a PDD (pervasive development disorder), the biological marker comprising a compound in a stool sample of the individual.

33. (New) The biological marker of claim 32, wherein the stool compound comprises chymotrypsin.

34. (New) The biological marker of claim 32, wherein the stool compound comprises an indicator of protein digestion.

35. (New) The biological marker of claim 32, wherein the stool compound comprises an indicator of pancreatic function.

36. (New) The biological marker of claim 32, wherein the PDD comprises autism

37. (New) The biological marker of claim 32, wherein the biological marker comprises a quantitative level of the stool compound.

38. (New) The biological marker of claim 37, wherein the biological marker is indicative of the need for biological treatment.

39. (New) A method for monitoring the course of a PDD (pervasive development disorder) in a patient diagnosed with the PDD, comprising monitoring a biological marker in each of a plurality of stool samples of an individual provided over a period of time.

40. (New) The method of claim 39, wherein the step of monitoring comprises measuring a quantitative level of the biological marker in the stool, wherein a change in a quantitative level is indicative of a change in the PDD condition.

41. (New) The method of claim 39, wherein the PDD comprises autism, ADD (attention deficit disorder) or ADHD (attention deficit hyperactivity disorder).

42. (New) The method of claim 39, wherein the PDD comprises a developmental delay.

43. (New) The method of claim 39, wherein the biological marker comprises chymotrypsin.

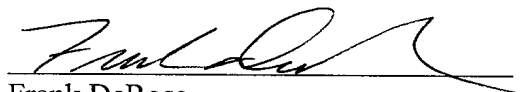
44. (New) The method of claim 39, wherein the biological marker comprises an indicator of protein digestion.

45. (New) The method of claim 39, wherein the biological marker comprises an indicator of pancreatic function.

**REMARKS**

Entry of the Preliminary Amendment prior to the examination of the above-identified divisional application on the merits is respectfully requested. The claims for the above-identified divisional application correspond to the non-elected claims (Group I) of the parent application U.S. Serial No. 09/466,559 filed on December 17, 1999, as set forth in the Election/Restriction requirement of October 10, 2001. No new matter has been added by the Preliminary Amendment. A substitute page 1 is annexed hereto illustrating the above amendment to the specification. Early and favorable consideration of this application is requested.

Respectfully submitted,



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# METHODS FOR TREATING PERVASIVE DEVELOPMENT DISORDERS

## Cross-Reference To Related Application

This application is a Divisional of U.S. Application Serial No. 09/466,559,  
5 filed on December 17, 1999.

## BACKGROUND

### **1. Technical Field:**

10 The present invention relates generally to a method for treating individuals  
diagnosed with a form of PDD (pervasive development disorder) and other  
disorders such as ADD (attention deficit disorder) and ADHD (attention deficit  
hyperactivity disorder). More specifically, the present invention is directed to  
therapeutic method for treating individuals with such disorders by administering  
secretin, other neuropeptides, peptides, and/or digestive enzymes, as well as a  
prognosticative method for determining the potential effectiveness of the  
15 administration of secretin, other neuropeptides, peptides, and/or digestive enzymes  
for the treatment of such disorders.

### **2. Description of Related Art:**

20 PDDs are a class of disorders defined by both American and International  
diagnostic systems (i.e., the Diagnostic and Statistical Manual of Mental  
Disorders, 4th edition (DSM-IV) and World Health Organization: International  
Classification of Diseases, Tenth revision (ICD-10)). The spectrum of PDDs  
include disorders such as Autism, Aspergers, ADD, and ADHD. PDDs are